Medicare Prescription Drug Inflation Rebate Program 340B Data Repository

Analysis of Proposed CY 2027 Reporting Requirement and Impact on 340B Hospitals
August 20, 2026

Provision and Location in the Proposed Rule

The provision appears in the CY 2027 Medicare Physician Fee Schedule proposed rule, CMS-1848-P, under Section III.F., "Medicare Prescription Drug Inflation Rebate Program," in the discussion of the Medicare Part D Claims Data 340B Repository. The principal policy discussion is at Federal Register pages 44012-44014. The administrative burden estimates appear at 91 FR 44223-44224, and the proposed regulatory text appears at 91 FR 44287 (§ 424.516(f)(4)) and 91 FR 44299-44300 (§ 428.203(c)).

- 91 FR 44012: CMS proposes to convert participation in the 340B repository from voluntary to mandatory beginning in 2027 and connects reporting to maintaining Medicare enrollment.
- 91 FR 44013: CMS describes the claim-level information to be reported, quarterly reporting, and the potential use of Medicare enrollment enforcement for noncompliance.
- 91 FR 44014: CMS explains that the submitted data would not be used to calculate Part D inflation rebates under this proposal; the repository would instead be used to test the usability and reliability of the data submission process.

Reference: *91 FR 44012-44014, 44223-44224, 44287, 44299-44300.* *Federal Register PDF*

Detailed Analysis

1. Mandatory reporting beginning January 1, 2027. CMS proposes that, for claims with dates of service on or after January 1, 2027, Medicare providers and suppliers that are 340B covered entities submit information associated with applicable Part D 340B claims to the repository. The proposal would replace the voluntary approach used for 2026 with a mandatory reporting obligation.

The requirement would extend beyond prescriptions dispensed directly by a hospital-owned outpatient pharmacy. It would also encompass 340B drugs dispensed through contract pharmacies and claims subsequently identified as 340B through retrospective replenishment arrangements. For hospitals that use multiple contract pharmacies or third-party administrators, this would require collection, reconciliation, and certification of claims data originating across multiple systems and organizations.

Reference: *91 FR 44012-44013.* *Federal Register PDF*

2. Claim-level data submission. For each applicable Part D 340B claim, CMS proposes requiring information such as the date of service, prescription or service reference number, fill number, dispensing pharmacy NPI, NDC-11, the covered entity's 340B ID, and the covered entity name as reflected in OPAIS. This is therefore not an aggregate annual utilization report; it is a recurring claim-level reporting obligation.

Reference: *91 FR 44013; proposed § 428.203(c), 91 FR 44299-44300.* *Federal Register PDF*

3. Quarterly submissions. CMS proposes that each calendar quarter's data be submitted by the end of the following calendar quarter, with more frequent reporting permitted. In practical terms, hospitals would have to create an ongoing process for collecting, reconciling, validating, and submitting Part D 340B claims data four times each year.

Reference: *91 FR 44013.* *Federal Register PDF*

4. Hospital responsibility for TPA or vendor submissions. CMS would permit a covered entity to use a 340B third-party administrator or other vendor to make the submission. However, the covered entity would remain ultimately responsible for the accuracy and completeness of the data. Thus, outsourcing the mechanics of reporting would not shift regulatory accountability away from the hospital.

For hospitals with substantial contract-pharmacy networks, this is a significant compliance concern. A hospital could face consequences because of incomplete or inaccurate information supplied by a TPA or pharmacy over which the hospital does not have direct operational control. It may also require new contractual protections, audit rights, data-validation procedures, and internal compliance resources.

Reference: *91 FR 44013-44014.* *Federal Register PDF*

5. Certification of completeness and accuracy. CMS proposes that the hospital or an authorized representative certify that the reported claims are verified 340B claims, that all applicable Part D 340B claims for the reporting period are included, and that the information is complete and accurate. Incomplete or invalid submissions would need to be corrected and resubmitted.

This certification obligation could be particularly difficult where a covered entity uses retrospective replenishment methodologies. Claims may be identified as 340B only after the underlying Part D transaction occurs, and hospitals may be dependent on external data flows to determine final 340B status. A certification that a quarterly submission contains all applicable claims therefore creates additional compliance exposure beyond the technical act of transmitting data.

Reference: *91 FR 44013-44014.* *Federal Register PDF*

6. Medicare enrollment enforcement is the most consequential element. CMS proposes adding § 424.516(f)(4) to make the reporting requirement part of the obligations for enrolling and maintaining active enrollment status in Medicare. CMS also states that it would reserve the right to use its existing revocation authority under § 424.535(a)(10) for failure to satisfy the documentation requirement.

For a hospital, loss of Medicare enrollment or the associated provider agreement would be an extraordinarily severe consequence. Medicare participation is central to hospital operations, reimbursement, and patient access. The proposed enforcement mechanism is therefore potentially disproportionate to a reporting failure that could involve a late filing, a data-quality problem, a vendor error, or an incomplete set of pharmacy claims.

Reference: *91 FR 44013; proposed § 424.516(f)(4), 91 FR 44287.* *Federal Register PDF*

7. CMS does not propose to use the 2027 repository data to calculate inflation rebates. CMS states that the data submitted to the 340B repository would not be used to calculate Part D inflation rebates under this proposal. CMS would continue using its existing Prescriber-Pharmacy Methodology to remove 340B units from Part D inflation rebate calculations. The agency instead proposes mandatory reporting in order to evaluate whether the repository data could be used reliably in the future.

This is a particularly important policy concern. CMS would impose a mandatory claim-level reporting obligation backed by the potential loss of Medicare enrollment even though the information is not needed to perform the rebate calculation under the proposed rule. In practical terms, hospitals would be compelled to participate in what remains substantially a repository testing and data-validation exercise, with potentially severe consequences for noncompliance.

Reference: *91 FR 44014.* Federal Register PDF

8. Significant nationwide administrative burden. CMS estimates that approximately 14,000 340B providers would submit information four times per year, resulting in approximately 56,000 quarterly responses, 462,000 total burden hours, and approximately $52.37 million in annual compliance costs.

For large 340B hospitals, those estimates may understate the actual burden because they may not fully capture upstream activities such as contract-pharmacy reconciliation, TPA oversight, correction of mismatched claims, legal review of vendor agreements, internal compliance review, certification, and remediation of rejected records.

Reference: *91 FR 44223-44224.* Federal Register PDF

9. Statutory-authority and proportionality concerns. CMS relies on Medicare documentation and enrollment authorities, including sections 1866(a)(1)(X) and 1842(h)(9) of the Social Security Act, to support the reporting mandate and its connection to enrollment. A hospital can reasonably ask CMS to explain why those authorities permit the agency to condition continued Medicare enrollment on participation in a specialized 340B claims repository whose data will not yet be used to calculate inflation rebates.

The stronger comment position is not necessarily to assert categorically that CMS lacks authority, but to question whether the proposed use of Medicare enrollment sanctions is reasonably related and proportionate to the reporting requirement. CMS should be urged to distinguish between intentional or repeated refusal to comply and ordinary good-faith data errors, vendor failures, or technical submission problems.

Reference: *91 FR 44013 and authorities cited by CMS in the proposed rule.* Federal Register PDF

Key Concerns for a 340B Hospital

- The proposal turns an experimental or validation-oriented data repository into a mandatory federal reporting program.
- The hospital would bear responsibility for claim data generated and transmitted by contract pharmacies, TPAs, and other third parties.
- Quarterly claim-level reporting would create new administrative, IT, compliance, reconciliation, and vendor-management costs.
- The hospital would be required to certify completeness and accuracy even where final 340B status may depend on retrospective replenishment and third-party data.
- The potential sanction—revocation of Medicare enrollment—is substantially more severe than the underlying data-reporting failure.
- CMS acknowledges that it does not plan to use the 2027 repository data to calculate Part D inflation rebates, weakening the justification for making reporting an enrollment condition at this stage.
- CMS should, at a minimum, establish notice, cure periods, materiality thresholds, safe harbors for good-faith errors, and graduated enforcement before any Medicare enrollment action is available.

Reference: *91 FR 44012-44014, 44223-44224, 44287, 44299-44300.* Federal Register PDF

Proposed Hospital Comment Language

We recommend using either of the following paragraphs as part of a FY27 PFS comment letter:

"We are deeply concerned with CMS's proposal to make submission of Part D 340B claims data to the Medicare Part D Claims Data 340B Repository a condition of a 340B hospital's continued enrollment in Medicare. The proposed requirement would impose a substantial new claim-level reporting obligation on 340B hospitals, including quarterly reporting of utilization occurring through contract pharmacies and retrospective replenishment arrangements. Hospitals would remain ultimately responsible for the completeness and accuracy of information submitted by their TPAs and other contractors and would be required to certify that the submission captures all applicable Part D 340B claims. CMS itself estimates that the mandate will impose more than 462,000 hours of annual administrative burden and approximately $52 million in costs nationally. For hospitals already subject to extensive and growing federal reporting, auditing, recertification, and 340B compliance requirements, this proposal would add significant expense and operational complexity without improving the delivery of care to Medicare beneficiaries."

"We are especially concerned that CMS proposes to enforce this new requirement through its Medicare enrollment authority, including reserving the right to revoke a hospital's Medicare enrollment for noncompliance, while simultaneously acknowledging that the data collected under the proposal will not be used to calculate Part D inflation rebates. CMS instead proposes to continue using its existing Prescriber-Pharmacy Methodology while requiring hospitals to submit these data so that the agency can test whether the repository might be usable for a different methodology in the future. Threatening the Medicare participation of a hospital because of a late, incomplete, or technically deficient submission to what remains essentially a data-testing initiative is disproportionate to the purpose of the requirement and could create enormous financial and patient-access consequences wholly unrelated to the underlying reporting deficiency. We urge CMS not to finalize the Medicare enrollment sanction and instead continue voluntary reporting, or at minimum establish a reasonable corrective-action process, materiality threshold, and meaningful safe harbor for good-faith reporting errors before any enforcement action may be taken."

Reference: *91 FR 44012-44014; proposed § 424.516(f)(4), 91 FR 44287; burden estimates at 91 FR 44223-44224. Federal Register PDF*

Primary References

Federal Register, Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (July 16, 2026): https://www.govinfo.gov/content/pkg/FR-2026-07-16/pdf/2026-14327.pdf

CMS, CY 2027 Medicare Physician Fee Schedule Proposed Rule (CMS-1848-P): https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1848-p

Key Federal Register pages: 44012-44014 (policy); 44223-44224 (burden); 44287 (§ 424.516(f)(4)); 44299-44300 (§ 428.203(c)).